

India US - Import Alert

Why in news?

\n\n

The stock of Divi's Laboratories dropped over 20% following the announcement that one its facility has received an import alert from the US drug regulator U S Food and Drug Administration (FDA).

\n\n

What is import alert?

\n\n

\n

- Companies that sell medicines in the US market are required to comply with the regulations mandated by the FDA.

\n

- Manufacturing units that supply drugs to the US are inspected by the FDA periodically.

\n

- If they find any lapses in the adherence to the mandated regulations, the same is notified by the FDA in Form 483 as observations.

\n

- This is the first level of action by the FDA in case of deviation from the **good manufacturing practices (GMP)**.

\n

- The company is given time to respond to the observations.

\n

- If the reply is not convincing the FDA may issue a warning letter.

\n

- This letter restricts the ability of that manufacturing unit to supply drugs to the US from that facility.

\n

- Then the company has to appoint consultants to advice on corrective actions and its monitor implementation.

\n

- After this, it approaches the FDA for re-inspection.

\n

- If the FDA is not satisfied again, it issues an **import alert**.
\n
- This implies a ban on the facility from supplying drugs to the US.
\n
- However, there have been instances where the FDA has directly issued an import alert even without an initial warning letter.
\n

\n\n

Why is it important?

\n\n

- \n
- The US is the largest pharmaceutical market in the world.
\n
- The share of Indian pharma companies in the US market has risen significantly over the past few years, catering nearly 40% of its pharma drug requirement.
\n
- Many patents are expected to expire in the upcoming years, opening a huge market for generic drugs from India.
\n

\n\n

- \n
- So to an investor in pharma stocks, it is important to keep a close tab on the regulatory action by the FDA as they can pose growth risks.
\n
- The progression of observations into import alerts and warning letters has been increasing of late.
\n
- So investors need to focus on the speed with which a company resolves these issues.
\n

\n\n

\n\n

Source: Business Line

\n



SHANKAR
IAS PARLIAMENT
Information is Empowering